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09/435992

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/435992	11/08/99	HANNA	N 012712-721

EXAMINER

HM22/0703  
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ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 07/03/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/16/01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-56 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☐ Claim(s) \_\_\_\_\_ is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☒ Claim(s) 1-56 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). NOW E FILED  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

### DETAILED ACTION

1. Applicant's election without traverse of Group I (claims 1-41) and the species Group B, including the use of an anti-CD40L specific antibody and an anti-CD20 antibody in Paper No. 12 is acknowledged.

It is noted that while applicant elected the use of an anti-CD40L specific antibody and an anti-CD20 antibody; applicant asserts that the use of anti-CD40L alone should be searched as well.

Again for clarity, applicant is invited to elect either anti-CD40L antibody alone or the combination of an anti-CD40L specific antibody and an anti-CD20.

Applicant is invited to consider indicating that the use of the art known chemotherapeutics and radiotherapy were obvious in treating CD40+ malignancies, particularly B cell lymphomas and B cell leukemias.

Therefore, applicant's election of either anti-CD40L antibody alone or the combination of an anti-CD40L specific antibody and an anti-CD20 would be considered in combination with the art known use of chemotherapeutics and radiotherapy were obvious in treating B cell lymphomas and B cell leukemias.

2. In the interest of compact prosecution and clarity; applicant is invited to indicate that the plurality of species set forth in claims 13-19 and 36-41, as they read on radiolabels and chemotherapeutics were obvious variants in the treatment of B cell lymphomas and leukemias at the time the invention was made.

If not, then applicant should elect a species for radiolabels and chemotherapeutics accordingly.

Particularly, with respect to the chemotherapeutics, the claimed chemotherapeutics are distinct because their structures and modes of action are different.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Upon reconsideration and for clarity, the following election species is set forth.

Claims 1-41 are generic to a plurality of disclosed patentably distinct species comprising . Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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This application contains claims directed to the following patentably distinct species of the claimed Group I : wherein the CD40+ malignancy is:

- A) a B-cell lymphoma or
- B) a B cell leukemia.

If a B cell lymphoma is elected; then this application contains claims directed to the following patentably distinct species of the claimed Group I : wherein the B cell lymphoma is:

- A) Hodgkin's Disease or
- B) Non-Hodgkin's Disease.

If a non-Hodgkin's Disease is elected; then this application contains claims directed to the following patentably distinct species of the claimed Group I : wherein the non-Hodgkin's Disease is selected from the group consisting of the species recited in claims 5 and 30.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

*Phillip Gambel*

Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
July 2, 2001